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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,066	05/29/2001	Thomas R. Fuerst	4600-0293.20	7789
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PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026				
EXAMINER FOLEY, SHANON A				
ART UNIT		PAPER NUMBER		
1648				

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,066

Applicant(s)

FUERST ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-33 is/are pending in the application.
- 4a) Of the above claim(s) 19-24 and 26-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

In the second paragraph of the "Remarks" section, applicant states that claims 25-33 are pending in the case. However, this statement is incorrect as claims 19-33 are pending.

It is also noted in the "Remarks" section that applicant states that claim 25 has been amended according to the examiner's suggestion. Upon review of the suggestion made on page 6 of the previous Office action (mailed 6/2/4) regarding claim 25, it is clearly evident that the phrase "including all of the limitations of the base claim and any intervening claims" was an inadvertent typo since this single phrase contradicts the issues raised in the body of the rejections against the limitations recited in the previously pending base claims 11-14 and 18. Since the rejected limitations in these previously pending claims are now present in claim 25, claim 25 is now rejected for the same reasons previously cited, based on applicant's amendment.

Election/Restrictions

Newly submitted claims 26-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 26-29 and claims 30-33 are drawn to nucleic acids, expression vectors, and expression system and a method of making an HEV polypeptide with a nucleic acid comprising another nucleic acid that is capable of hybridizing to a DNA encoding a polypeptide. Neither nucleic acid claimed in claims 26-29 or 30-33 have any discernable structural and/or functional relationship to the nucleic acid sequence of claim 25, which is under consideration. Each of the nucleic acids claimed in claims 26-29 and 30-33 would require a divergent and non-overlapping search due to the structural uniqueness of each nucleic acid. Further, the method of producing an

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HEV polypeptide composition of claims 29 and 33 can be practiced with either of the two materially different compositions described in claims 27 or 31.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In conclusion, claims 19-33 are pending in the application. Claims 19-24 and 26-33 are withdrawn from consideration due to a non-elected invention and claim 25 is under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claim is drawn to a substantially isolate nucleic acid encoding an amino acid sequence of SEQ ID NO: 15 or SEQ ID NO: 16 or an amino acid sequence having the amino acid terminus of SEQ ID NOs: 15 or 16 and a deletion of up to 24 amino acids from the carboxy terminus. The claim also encompasses amino acid sequences that are at least 70% homologous

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to any of the aforementioned sequences. The claim does not require that the sequences possess any particular distinguishing feature, biologic activity, or conserved structure. Therefore, the claims are drawn to a genus of sequences that are defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure of the sequences that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of sequences, given that the specification has only described SEQ ID NOs: 15 and 16 and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and

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reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only substantially isolated nucleic acids encoding an amino acid sequence of SEQ ID NO: 15 or SEQ ID NO: 16 or an amino acid sequence having the amino acid terminus of SEQ ID NOs: 15 or 16 and a deletion of up to 24 amino acids from the carboxy terminus of SEQ ID NOs: 15 or 16, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph (emphasis added). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by (Genseq database accession no: AAQ27436. First entry: February 5, 1993 of Patent No: JP04200388-A).

It has been previously determined that the instant claims receive the benefit of the filing date of parent application 08/327952, viz. October 24, 1994. Therefore, AAQ27436 is applicable under 35 U.S.C. 102(b).

Claim 25 is drawn to a substantially isolated nucleic acid sequence encoding a polypeptide derived from the carboxy-terminal 549 amino acids of HEV ORF2, wherein the

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amino acid sequence is selected from SEQ ID NO: 15 and has a sequence homology of at least 70%.

The nucleic acid sequence of AAQ27436 is 98.11% similar to the instant SEQ ID NO 15, see the sequence alignment provided and "Percent Similarity".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

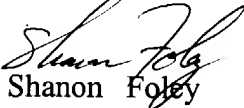
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
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